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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,349	07/23/2004	Ali Rezai	12637/71	6084

23838 7590 12/06/2007
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EXAMINER

DIETRICH, JOSEPH M

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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12/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/502,349

Applicant(s)

REZAI ET AL.

Examiner

Joseph M. Dietrich

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-35 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4, 19, 20, 22, 24, 36, 38, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Baudino et al. (U.S. Patent 6,353,762).

Regarding claims 1 and 4, Baudino discloses a method of affecting chronic pain in a patient comprising: a) implanting a stimulator in a target site of the brain (e.g. column 9, lines 61 – 66); and b) providing stimulation to the stimulator to stimulate the target site to affect chronic pain (e.g. column 9, lines 18 – 24), the target site selected from the group consisting of the anterior limb of the internal capsule (e.g. column 9, line 66).

Regarding claims 19, 20, 22, 24, and 36, Baudino discloses the target site is selected from the group consisting of the anterior nucleus of the thalamus (e.g. column 9, line 67), the dorsomedial nucleus of the thalamus (e.g. column 9, line 67), the lateral hypothalamus (e.g. column 10, line 3), and the ventral pallidum (e.g. column 9, line 65).

Regarding claims 38 and 40, Baudino discloses a method of affecting chronic

Art Unit: 3762

pain comprising: a) implanting a stimulator in communication with a pain circuitry target site of either claim 1 or claim 19 (e.g. column 9, lines 61 – 67); b) detecting a bodily activity of the body associated with chronic pain (e.g. column 2, lines 57 – 60); c) providing a stimulation signal to the stimulator in response to the detected bodily activity (e.g. column 2, lines 60 – 62); and d) stimulating the target site to affect the chronic pain (e.g. column 9, lines 18—24).

3. Claim 37 is rejected under 35 U.S.C. 102(b) as anticipated by MacDonald et al. (U.S. Patent 5,776,170).

Regarding claim 37, MacDonald discloses a method of affecting chronic pain comprising: a) implanting a stimulator in communication with a pain circuitry target site (e.g. column 8, lines 55 – 57); and b) providing a stimulation signal to the stimulator to stimulate the synthesis or release of an endogenous opioid (e.g. column 3, lines 28 -31) to affect chronic pain (e.g. column 10, lines 4 – 6 and Table 2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3762

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 19, 21, 26 – 31, and 33 – 35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schiff (U.S. Patent 5,938,688).

Regarding claims 19, 21, 26 – 31, and 33 – 35, Schiff discloses a method of affecting chronic pain in a patient comprising: a) implanting a stimulator in a target site of the brain (e.g. column 1, lines 9 – 10); and b) providing stimulation to the stimulator to stimulate the target site to affect chronic pain (e.g. column 2, lines 20 – 23 and lines 43 – 47), the target site selected from the group consisting of the intralaminar thalamic nuclei (e.g. column 4, lines 58 – 61), locus coeruleus (e.g. column 8, line 20), dorsal raphe nucleus (e.g. column 8, line 20), substantia nigra pars compacta (e.g. columns 9 and 10, Table 1), substantia nigra pars reticulata (e.g. columns 9 and 10, Table 1), superior colliculus (e.g. columns 9 and 10, Table 1), tegmentum (e.g. column 8, line 19), medial thalamus (e.g. column 14, lines 45 – 50), nucleus accumbens (e.g. column 13, lines 5 – 6), ventral striatum (e.g. column 8, line 2). Because Schiff discloses that patients with impaired cognitive function accompanied by chronic pain can benefit from the practice of Schiff's invention, Schiff teaches that chronic pain is affected by this method. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Schiff so as to treat patients with only chronic pain, since such a modification would provide the predictable results of affecting chronic pain.

Art Unit: 3762

7. Claims 1 - 3, 8 - 10, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff (U.S. Patent 5,938,688).

Regarding claims 1 - 3, 8 - 10, 17, and 18, Schiff discloses the target site is selected from the group consisting of the pre-frontal cortex (e.g. column 7, line 48), orbitofrontal cortex (e.g. column 7, line 54), cingulate cortex (e.g. column 7, lines 58 - 59), anterior cingulated cortex (e.g. column 7, lines 58 - 59), and posterior cingulated cortex (e.g. column 7, lines 58 - 59), amygdala (e.g. column 14, lines 10 - 20), and hippocampus (e.g. column 14, lines 10 - 20). Schiff fails to disclose that the stimulator is implanted in any of these cortical sites. Instead, Schiff discloses that the stimulator is implanted in the intralaminar nuclei (e.g. column 1, lines 9 - 10). However, Schiff teaches that the intralaminar nuclei project to these cortical sites and therefore stimulate these cortical sites. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulator as taught by Schiff with a stimulator that is implanted directly in the cortical sites, since such a modification would provide the predictable results providing direct stimulation to these cortical sites even in the event that the intralaminar nuclei are injured.

8. Claims 1 - 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino or Schiff.

Regarding claims 1 - 36, although Baudino and Schiff fail to explicitly state stimulating the insular cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medial frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, and the tectum, these

Art Unit: 3762

references do teach that it is known to stimulate other cortical sites (e.g. the pre-frontal cortex) and other deep brain sites (e.g. the intralaminar nuclei) in order to affect chronic pain. It would have been obvious to one having ordinary skill in the art at the time the invention was made to try to stimulate these other cortical and deep brain sites in the brain since these references teach that it is known to stimulate cortical sites and deep brain sites to affect chronic pain and there are a finite number of cortical sites and deep brain sites.

Response to Arguments

9. Applicant's arguments with respect to claims 1 – 38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is 571-270-1895. The examiner can normally be reached on Mon - Fri, 8:00AM - 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD
JMD
11/27/07

GEORGE R. EVANISKO
PATENT EXAMINER

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